| Title: **Preparation of TRC Standard Operating Procedures** | Procedure Number: **QA-001** |
|---|---|
| | Revision Number: 01 |
| Supersedes: QA-001, Revision 00 | Issued Date: 1/7/11 |
| Reason for Revision: Rev. 01: Routine update. | Effective Date: 1/17/11 |

| Authorization Signatures | | |
|---|---|---|
| Author — Date: 1/7/11 | Functional Area Manager — Date: 1/7/11 | Quality Assurance — Date: 1/7/11 |

## 1.0 PURPOSE, SCOPE, AND APPLICABILITY

This procedure describes the function of TRC standard operating procedures (SOPs) used by select TRC Sectors and/or Practices (i.e., at the discretion of the Sector Director or Practice Leader), describes the recommended content of these SOPs, and establishes the sequence of activities in the preparation and revision of theseTRC SOPs.

This procedure is applicable to the preparation of TRC Sector-specific and/or Practice-specific SOPs that describe activities performed by TRC project personnel and standardizing the practices and procedures of the activity is desired. Project-specific SOPs may vary based on client directives; however, the contents in this procedure will be used as reference material to guide the process of preparing project-specific SOPs.

## 2.0 REFERENCES

American National Standard ANSI/ISO/ASQ Q9000-2005, *Quality Management Systems – Fundamentals and Vocabulary*

TRC SOP QA-002: Document Control Procedures.

## 3.0 DEFINITIONS

**Cancellation Notice –** A written notification that a document is no longer effective. Cancellation notices shall be issued for all discontinued and superseded controlled documents and are recommended for other quality-related discontinued and superseded documentation.

**Change Notice –** A written notification of revisions to an approved document. Change notices shall be issued for all revisions to controlled documents and are recommended for TRC SOPs and quality-related documentation.

**Controlled Document –** A document for which distribution is controlled by the designation of a unique, controlled copy number and documented assignment to a specified individual or organization. Recipients of controlled documents automatically receive revised documents.

**Effective Date –** The date an SOP (original issue or revision) becomes effective.

**Functional Area Manager –** A TRC employee who has management authority and responsibility for a specific Sector, Practice, activity, or group of TRC personnel (e.g., Sector Director, Practice Leader, Office or Group Manager).

**Issued Date –** The date an SOP (original issue or revision) is published and distributed. TRC SOPs are not effective until the review and approval process is completed.

**Quality Assurance –** All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality. (ISO-8402)

**Quality Control –** The operational techniques and activities that are used to fulfill requirements for quality.

**Shall, Must, or Will –** The words used to indicate a mandatory requirement that must be met.

**Should or May –** The words used to denote a recommended practice or guideline.

**Standard Operating Procedure (SOP) –** Formal, revision-controlled, written documents that:

- Define the methods used by TRC staff in the performance of quality-affecting activities, findings, or conclusions.
- Provide standardized methods for implementation of work so as to maximize, as appropriate, uniformity and reliability of products and services.
- Facilitate coordination among individuals performing separate but inter-related tasks.

When the standardized methodologies are inappropriate for a specific project or task, project documentation (e.g., work plan, QA plan) specifies the project-specific procedures to be implemented.

## 4.0 SUMMARY OF RESPONSIBILITIES

Functional Area Managers (e.g., Practice Leader, Sector Director) are responsible for:

- Designating requirements for the preparation and implementation of Sector- or Practice-specific SOPs (e.g., Which SOPs should be written and used, if any. Will use on projects be required or optional?).
- Designation of SOPs to be managed as "controlled documents".
- Obtaining qualified technical review of new and/or revised SOPs.
- Review and approval of new and revised area-specific SOPs.
- Determining the distribution of approved area-specific SOPs and notices.

Quality Assurance personnel are responsible for:

- Review and approval of new and revised TRC SOPs.
- Assisting the Functional Area Managers in preparing change and cancellation notices, when appropriate.

- Assisting the Functional Area Managers in determining the appropriate SOPs to be prepared and assignment of procedure numbers.

SOP Authors are responsible for preparing and/or revising SOPs in accordance with the requirements of this procedure.

SOP Peer Reviewers are responsible for providing review comments of drafts submitted to them for review within the specified review schedule.

TRC Staff are responsible for:

- Performing tasks in accordance with the pertinent SOPs (or project-specified procedures).
- Assisting in the preparation and revision of accurate and practical SOPs.

## 5.0 SAFETY CONSIDERATIONS

No specific safety considerations are associated with the preparation of TRC SOPs.

## 6.0 PROCEDURE

### *6.1 Preparation and/or Revision of SOPs*

New TRC SOPs or revisions to existing SOPs may be initiated by any TRC employee by obtaining approval from the Functional Area Manager associated with the activity described in the SOP. New or revised SOPs should be initiated when one or more of the following occurs:

- Quality-affecting activities are identified that are not addressed in an existing SOP.
- Problems are encountered when implementing an existing SOP.
- A new SOP or revision to an SOP could prevent the recurrence of problems encountered.
- Regulatory, professional standards, or other technical updates or revisions to the SOP subject matter have been published.

If the Functional Area Manager considers the preparation or revision appropriate, this individual will assign responsibility for the SOP preparation or revision to the requestor, to a member of the Quality Assurance staff, and/or to other TRC personnel, as appropriate.

### *6.2 SOP Contents*

TRC SOPs should be prepared in the same format as this SOP and shall include, at a minimum, the following elements and information:

> ***Note:*** As long as all concepts described in Section 6.2 of QA-001 are incorporated, a Practice or Functional Area may choose to reorganize the content of the SOPs written for use within that Practice.

- **Title Block –** Included on the first page of the SOP with abbreviated title block information in the footer of subsequent pages. The title block will include the following information:
  - *Title* providing sufficient descriptive information to identify the subject of the procedure.

- *Procedure Number* which is a unique alphanumeric identifier assigned to the SOP following the convention of XX - # # # where XX is a two-letter acronym designating the functional area and # # # is a three-digit sequential number. For example, this procedure is assigned Procedure Number: QA-001.
- *Revision Number* indicating the number of approved revisions. The original approved SOP is assigned revision number "00" with subsequent approved revisions indicated by number.
- *Issued Date* indicating when that revision of the SOP is distributed, following authorization approvals.
- *Effective Date* indicating the date after which the approved SOP is operative. All approval signatures shall be obtained on or before the effective date.
- References to documents or SOPs that are replaced by the approved SOP are listed under the *Superseded by* section.
- A brief statement(s) describing the *Reason for Revision*.
- *Authorization Signatures* indicating approval of the SOP including, but not limited to, the SOP Author, cognizant Functional Area Manager, and a QA representative.

- **Section 1 – Purpose, Scope, and Applicability:** An explanation of the objectives of the procedure, typical applications, and limitations or restrictions on the procedure's application.
- **Section 2 – References:** Identify pertinent interfacing documents or procedures. All references should include sufficient detail (e.g., complete title, document number, revision) such that the user is able to locate the reference materials.
- **Section 3 – Definitions:** Define words and phrases that are unique to the procedure or that may provide a key to understanding responsibilities and specified actions.
- **Section 4 – Summary of Responsibilities:** Identify the individual(s) (by title or organizational position) or organization(s) responsible for implementation of the activities described in the procedure and provide a brief summary of respective responsibilities.
- **Section 5 – Safety Considerations:** Describe appropriate personnel protective equipment, actions required to prevent injury, and any other applicable health and safety considerations or procedures. If this section is not required or is inappropriate to the activities in the SOP, the heading will remain with a statement to the effect that the section is "Not Applicable".
- **Section 6 – Procedure:** Identify the step-by-step sequence of actions to follow. The procedure should be written clear enough, and in sufficient detail, to ensure that any two individuals performing the activity will achieve similar results. SOPs should not define methodologies in such detail as to impose unnecessary restrictions on the adaptability of a procedure to moderately varying project requirements.
- **Section 7 – Quality Control Procedures:** An outline of the quality control (QC) check procedures including frequency requirements and applicable acceptance criteria. For example, a frequent QC check procedure will be technical peer review of documents or reports and field QC samples (e.g., equipment blanks, field duplicates) that may be included in a sample collection effort.
- **Section 8 – Training and/or Qualifications:** The minimum skills, experience, specialized training, and educational background required of individuals performing the activities described in the procedure.

- **Section 9 – Forms, Records, and Documentation:** Identify the forms, worksheets, log sheets, and any other documentation requirements associated with the activities described in the SOP. Copies of example pre-formatted forms, worksheets, etc. should be attached for reference. As applicable, reference the records management procedure used for processing the documents.

### 6.3 Approval and Distribution of TRC SOPs

Upon completion of peer review and subsequent changes to the document, the author shall obtain approval from the Functional Area Manager and a Quality Assurance staff representative. Approval is signified by dated authorization signatures in the SOP title block.

Distribution of approved SOPs will be coordinated by the Functional Area Manager and the applicable Quality Coordinator (e.g., Practice Quality Coordinator, Quality Management Director).

### 6.4 Revision of TRC SOPs

Revision of SOPs may be initiated by any individual, as specified in Section 6.1 of this procedure. Significant revisions that result in the addition (or deletion) of text should be either "highlighted" in the text (e.g., track changes) or summarized in an attached cover page for purposes of the internal reviews. Revised SOPs are subject to the same review and approval process as the original document.

### 6.5 Change and Cancellation Notices

Change notices (Figure 1) may be distributed when revisions to the SOP are not extensive enough to warrant re-issuance of an SOP, but where notifying users of the SOP of pertinent information is important. The maximum number of change notices issued prior to reissuing the SOP is three.

Cancellation notices (Figure 1) should be issued whenever an SOP is superseded by another SOP or when an SOP becomes obsolete.

Distribution of change and cancellation notices is left to the discretion of the Functional Area Manager and QA personnel.

TRC SOP QA-002 (*Document Control Procedures*) describes the use of change and cancellation notices in more detail.

## 7.0 QUALITY CONTROL PROCEDURES

All new or revised SOPs shall be reviewed by a minimum of one qualified technical peer reviewer, the Functional Area Manager, and a QA staff representative. Comments from all reviewers will be incorporated and/or resolved through discussion with the reviewers.

## 8.0 TRAINING AND/OR QUALIFICATIONS

The preparation of SOPs should be implemented by individuals who meet the training and/or qualifications requirements specified by the Functional Area Manager for the activities described in the procedure. The technical peer review will be conducted by an individual qualified to both implement and/or supervise others in the implementation of the SOP.

## 9.0 FORMS, RECORDS, AND DOCUMENTATION

Documentation generated because of this SOP includes the approved SOPs, change notices, and cancellation notices. Original copies of the approved SOPs, change notices, and cancellation notices will be maintained by the Functional Area Manager with a copy (controlled copy if issued as a controlled document) distributed to TRC's Quality Management Director.

A Microsoft Word file containing a template of the SOP format described in this SOP is available for use, if desired.

No additional forms, records, worksheets, or other documentation are required to be used or maintained because of preparing or revising an SOP.

## Change or Cancellation Notice

| Change / Cancellation Notice No.: (circle one) | Effective Date of Change / Cancellation: (circle one) |
|---|---|
| Document Title:<br><br>Revision No. and Date: | |
| Purpose or Basis for Change or Cancellation: | |
| Summary of Change:<br>(Attach insert or replacement page(s) printed on goldenrod paper with original text shown on the top half and revised text on the bottom half of the page.) | |
| How to File:<br>❑ Insert attached replacement pages and destroy obsolete pages.<br>❑ Attach notice and insert pages to original document.<br>❑ Destroy entire obsolete document.<br>❑ Other, explain. | |

**APPROVALS**

| | Name (Type or Print) | Signature | Date |
|---|---|---|---|
| Document Sponsor: | | | |
| Quality Assurance: | | | |

**FOR DOCUMENT CONTROL USE ONLY**

| Logged in by: | Date: |
|---|---|

Revision 1
February 15, 2007

**Figure 1. Change or Cancellation Form**